IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF ANNE M. WEBER, M.D.

I. INTRODUCTION

Plaintiffs submit this opposition to defendants' motion to bar "in its entirety" the testimony of Anne M. Weber, M.D.[1] The motion should be denied because defendants mischaracterize and ignore Dr. Weber's core opinions and testimony. None of defendants' objections warrant the extraordinary relief they seek – a complete exclusion.

Dr. Weber is a leading urogynecologist in clinical research and treatment of prolapse treatment. She conducted the first randomized controlled trial comparing mesh kits to traditional suture repair. In 2007, after she stopped practicing medicine due to a personal medical condition, Dr. Weber was selected by the American Congress of Obstetricians and Gynecologists ("ACOG") to author a Practice Bulletin to guide gynecologists regarding best practices related to treating prolapse with mesh. She has authored 100 peer reviewed publications. Her massive reliance list is a testament to her diligence and academic rigor, and the strong foundation for her understanding of the issues she opines on. Dr. Weber's credentials were of such significance

[1] Dr. Weber is currently designated as an expert witness in two Wave 1 cases: *Melissa & Charles Clayton*, No. 2:12-cv-00489 and *Donna Loustaunau*, No. 2:12-cv-00666.

that she was chosen to create and head the program at the National Institutes of Health ("NIH") to fund research into the treatment of pelvic organ prolapse ("POP").

In short, Dr. Weber has been at the forefront of clinical research of POP treatment, clinical study of mesh, and issued a clarion call warning of the high risks posed by mesh in 2007. Her expertise was established and validated before this litigation began. Defendants' attempt to disingenuously pigeonhole Dr. Weber as a "professional expert witness" cannot withstand scrutiny. Indeed, **Ethicon's employees and internal documents admit her leading role** in the field. Finally, defendants also fail to disclose that courts in New Jersey, Pennsylvania and Missouri have all held that Dr. Weber is eminently qualified and permitted her to testify against Ethicon in previous Prolift bellwether trials, on all issues.

Recognizing the limited time available to present these cases, and the fact that Dr. Daniel Elliott has already given his trial deposition covering the design defect and failure to warn issues, for use in all Prolift trials, Dr. Weber intends to offer a narrower set of opinions, specifically:

- A discussion of the relative risks and benefits of the various alternative procedures for the treatment of POP, and that there was no need for the Prolift, and that the alternative procedures are safer alternatives;

- The results of and opinions flowing directly from her painstaking analysis of the raw clinical data, and governing protocols, for the prototype clinical studies conducted by and relied on by Ethicon to support the marketing of the Prolift, including significant discrepancies between her findings and the results reported by Ethicon;

- The results and opinions flowing directly from Dr. Weber's careful analysis of the data from the Ethicon-funded independent investigator study ("IIS") database, compiling the outcomes of over 500 patients treated by Dr. Vincent Lucente, who is one of the principal investigators for the Prolift prototype studies, a key Ethicon advocate and the author of numerous articles based on the IIS data (which grossly exaggerate the safety and efficacy of the Prolift, as uncovered by Dr. Weber's objective, scientific assessment of Dr. Lucente's data); and

- Dr. Weber's opinion, based on the clinical data, the medical literature and further supported by Ethicon's own internal documents and deposition admissions that the Prolift did not have an acceptable risk/benefit profile.

Defendants' motion should be denied.

II. FACTUAL BACKGROUND

Dr. Weber is a nationally and internationally respected urogynecologist whose *curriculum vitae* recites a distinguished career and notable achievements. *See* Anne Weber, M.D. CV (attached hereto as Ex. A). As set forth in the *curriculum vitae*, Dr. Weber has held numerous prestigious positions, including Director of Clinical Research for the Department of Gynecology and Obstetrics at the Cleveland Clinic, Founder and initial Director of the Urogynecology Fellowship Program at Magee Women's Hospital, University of Pittsburgh and Medical Officer, Program Director for Research on Female Pelvic Floor Disorders, Contraception and Reproductive Health Branch at the National Institutes of Health. *Id.*

In addition to her track record of training and teaching other physicians and numerous fellows, she holds a Masters of Science in Clinical Research Design and Statistical Analysis from the School of Public Health at the University of Michigan, and has a distinguished track record of structuring, conducting and evaluating clinical studies in the field of urogynecology. *Id*. Dr. Weber has been a peer reviewer for at least 15 medical publications, and she is an author of at least 100 publications in the peer reviewed literature. *Id*. Dr. Weber currently is a peer reviewer. *See Hammons v. Ethicon*, No. 3913 (Ct. Comm. Pleas Phila. Dec. 2015), 12/07/15, Vol. V, Trial Tr. 227:16-17 (attached hereto as Ex. B); *see also* Weber CV, p. 1.[2]

[2] Dr. Weber ceased practicing medicine due to a medical condition that made it too difficult for her to continue in that field. *Id*. at 232:18-233:33, *see id.* at 213:18-21.

Perhaps most ironic, in their litany of criticisms of Dr. Weber's credentials defendants fail to mention that the internal expert Ethicon relied on to assess whether the Prolift could be safely marketed, and that its warnings were adequate, was Worldwide Medical Director Charlotte Owens, who at that time was only four years out of her gynecology residency, and Ethicon's medical director did not consider herself to be an expert with regard to the use of mesh to treat prolapse. *See* Charlotte Owens 9/12/12 Dep. at pp. 14:20-22, 22:17-20, 24:8-11, 33:18-34:1, 53:1-53:5 (attached hereto as Ex. C). Dr. Weber's international reputation and credentials far eclipses those of Dr. Owens, and Dr. Weber simply addresses the issues that were within Dr. Owens' responsibilities. In fact, **in February 2006, Dr. Weber was identified in an internal Ethicon document as well-qualified to help establish a randomized controlled trial comparing the Prolift to anterior colporrhaphy,** one of the issues she will opine on at trial. *See* ETH.MESH.01782783-85 at 01782785 (attached hereto as Ex. D).

B. Courts have Repeatedly Held that Dr. Weber is Qualified & Admissible

The New Jersey Superior Court overseeing thousands of pelvic mesh cases has previously considered and denied a motion to preclude a broader range of Dr. Weber's opinions, including design defect and failure to warn, in the *Gross* trial. *See Gross v. Ethicon*, Tr. (Jan. 7, 2013), at 105:4-107:15, and (Jan. 17, 2013) at 1314:5-1327:24 (attached hereto as Ex. E). Since the *Gross* trial, Dr. Weber has continued to review key documents, literature, clinical data and depositions, and has only enhanced her knowledge of the facts and her credentials as an expert. And she has been qualified and admitted to testify in two additional Prolift trials: *Hammons v. Ethicon* in Pennsylvania and *Budke v. Ethicon* in Missouri. (attached hereto as Exs. B & F). In sum, Dr. Weber's qualifications and methodology has been validated.

C. Dr. Weber's Opinions

Dr. Weber's opinions will be consistent with the testimony she recently offered during the *Hammons v. Ethicon* trial in December 2015, in which she opined that the Prolift has a medically unacceptable risk/benefit profile for multiple reasons including but not limited to the following:

- Prolift has an unacceptable risk/benefit profile due to high recurrence and erosion rates in the clinical data, 25:1-26:22;

- Dr. Weber analyzed the raw patient-level data (the only expert ever to do so), and found that the data underlying the Gynemesh PS mesh study does not support the reported 80-90% success rate claimed by Ethicon, 27:4-31:22;

- Dr. Weber analyzed the raw patient-level data (the only expert ever to do so), and found that the French TVM Study, relied on by Ethicon, was flawed and unreliable because there was a protocol deviation by including patients with Stage II prolapse in study, 33:18-34:18; and due to improper POP-Q measurement techniques, 36:11-37:17;

- The reported results of the French TVM study were flawed because they did not include women who reported complications at the 6-month interval if the same women did not return at the 1-year interval, 38:17-40:2;

- The French TVM study demonstrates, when corrected, an unacceptable risk/benefit profile (20.7% mesh exposure rate at the 1-year interval, which is a failure under Ethicon's own standard), 41:10-42:11, *compare* 47:7-48:25 (in another clinical mesh trial, the clinicians halted a study at the 3-month interval when complication rate reached 15.6%); (attached hereto as Ex. G).

- The US TVM mesh exposure study, when the data is correctly reported, also shows an unacceptable risk/benefit profile, 45:21-47:1;

- Dr. Weber is the only expert to review the IIS database, and found that the clinical data in the database funded by Ethicon, and compiled by Dr. Vincent Lucente (an Ethicon investigator and key opinion leader), demonstrates an unacceptable risk/benefit profile, 60:25-61:13; and that the Abstract presented by Dr. Lucente to the International Urogynecological Association ("IUGA") did not accurately report the results in his IIS database – downplaying recurrence and erosion rates and relying on an improper POP-Q technique, 51:22-58:6;

- Ethicon's Clinical Expert Report for the Prolift – which was a medical report written by Dr. Owens to justify sale of the Prolift, relies in part on the foregoing studies and data, and medical literature – is not supported by sufficient clinical data to establish the device is safe and effective for widespread marketing, 62:2-64:7;

- The Lowman article (relied on by Ethicon) regarding dyspareunia is unreliable because the authors based their analysis on medical charts (16.7% reporting pain with sex) rather than the women-patients' questionnaires (39% reporting pain with sex), 64:16-65:8, 72:8-73:2;

- A medical article authored by the TVM group shows unacceptably high complication rates (33.6%) at a short interval (3.5 months), 73:7-75:5;

- The September 2006 Abstract presented by the French TVM group shows at short-range follow-up a significant number of complications – especially to sexual function of younger women, 75:12-77:16;

- Ethicon marketed Prolift to all patients including those with only Stage I and II prolapse, but the TVM French group showed the device was only suitable for Stage III and IV prolapse, 77:23-79:13;

- The June 2009 IUGA presentation by members of the French TVM group analyzing contraction problem (19.6%) and related scar plating, which ultimately results in vaginal distortion, demonstrate an unacceptable risk/benefit profile, 79:17-87:22;

- Dr. Weber's 2007 ACOG Bulletin on mesh devices and opinion that mesh kits like Prolift present significant risks, and should have been, and be, considered "experimental," 87:25-91:22,93:14-99:6.

Hammons 12/08/15 Trial Tr. (Vol. VI) 25:1-99:6 (attached hereto as Ex. B).[3] This overview of the opinions to be offered demonstrates that the testimony is rooted in clinical research and medical literature, the heart of Dr. Weber's qualifications and applied clearly sound methods.

[3] Plaintiff incorporates by reference the full testimony of Dr. Anne Weber from the *Hammons v. Ethicon* case as it is voluminous.

III. DR. WEBER IS EMINENTLY QUALIFIED

"The witness' qualifications to render an expert opinion are also **liberally** judged by Rule 702." *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993) (emphasis added). Dr. Weber's qualifications as a urogynecologist, teacher, researcher and author with regard to pelvic organ prolapse, pelvic floor disorders and the treatment thereof cannot be reasonably challenged.

A. Rule 702 Does Not Require a Medical License to be Qualified

Defendants do not object to the substance of Dr. Weber's qualifications, *i.e.*, there is no dispute regarding Dr. Weber's "knowledge, skill, experience, training, or education" as a leading urogynecologist. F.R.E. 702. Rather, defendants' primary swipe is that "Dr. Weber quit the practice of medicine in 2005" in order to become a "professional witness" in this litigation. (Def. Memo. 4). This characterization of Dr. Weber is false, and ignores the liberal standard under F.R.E. 702, which does not require a medical expert to be licensed or practicing medicine.

Contrary to defendants' spin, Dr. Weber did not "surrender" her medical license to become a "litigation expert." Rather, she developed a personal debilitating medical condition that prevented her from continuing her surgical practice and actively seeing patients on a daily basis, and consequently she no longer had need to maintain a medical license. *See Hammons* 12/07/15 Trial Tr. (Vol. V) at 232:18-233:33, 213:18-21 (Ex. B). The fact that a personal medical condition prevents Dr. Weber from continuing to treat patients does not in any way impair her qualifications. It is notable that in denying Ethicon's *Daubert* challenge to the opinion of plaintiff expert Dr. Daniel Elliott on anatomic recurrence rates, the Court found that the opinion was reliable based on three medical articles – two of which were authored by Dr. Weber. *See Bellew v. Ethicon, Inc.*, No. 2:13-22473, at *22 (S.D.W. Va. Nov. 20, 2014), *available at* Pacer D.E. 265.

Nor does Rule 702 provide that a medical expert is unqualified merely because she no longer maintains a medical license, due to a physical handicap or retirement. To the contrary, federal courts have repeatedly held that grafting such a requirement into the rule is error. *E.g.*, *Garnac Grain Co. v. Blackley*, 932 F.2d 1563, 1567 (8th Cir. 1991) (holding reversible error where district court excluded an expert who had retired from teaching and no longer was a licensed CPA; any "weaknesses in his opinion and expertise go to the weight to be given his testimony, not its admissibility.... it is for the jury to determine the value of his opinion."); *Hayduk v. City of Johnstown*, No. 3:2005-294, 2009 WL 3335339, at *2-3 (W.D. Pa. June 4, 2009) (holding that the "presence or **absence of an active medical license does not in any way [a]ffect [a physician's] ability to provide expert testimony** that would be helpful…. The status of an administrative licensure is not dispositive of Dr. Gress's capability as an expert: even a cursory review of his curriculum vitae reveals him to be an accomplished and decorated physician.") (emphasis added); *Eidson v. Wal-Mart Stores, Inc.*, No. 92-2172, 1993 WL 393795, at *2 (D. Kan. Sept. 9, 1993) (denying a plaintiff's *Daubert* motion based on defense expert "no longer an active practicing physician but works almost exclusively as a trial expert," as "the grounds asserted by the plaintiff go to the weight of [expert] testimony, not its admissibility"); *see also Grindstaff v. Coleman*, 681 F.2d 740, 742-43 (11th Cir. 1982) ("holding that a doctor or other expert need not be licensed on the date of the event about which he testifies," where expert was medical student at time of injury).

Here, defendants have not directly challenged or disputed Dr. Weber's credentials. "Inasmuch as the rule uses the disjunctive, a person may qualify to render expert testimony in **any <u>one</u> of the five ways listed**: knowledge, skill, experience, training, or education." *Kopf*, 993

F.2d at 377 (4th Cir. 1993) (emphasis added). And Dr. Weber's qualifications are to be evaluated in "the totality":

> It is clear that a background in just one of these five may be sufficient. For example, a witness with an academic background in a given area but no practical experience may still qualify as an expert. The same is true for a witness with experience but no formal education. However, most experts will have some background in more than one basis. In that case, **a court may consider the totality of a witness's background when evaluating the witness's qualifications** to testify as an expert. Assuming a witness's background qualifies that witness as an expert, the witness is competent to testify as an expert….

29 Charles A. Wright, et al., *Fed. Prac. & Proc. Evid.* § 6264.1 (2d ed.) (footnotes omitted, emphasis added). Consequently, the lack of a medical license cannot serve to disqualify Dr. Weber. [4]

B. Rule 702 Does Not Require Dr. Weber to Implant a Prolift to be Qualified

Defendants concede that experience with the Prolift is not required to be qualified: "Ethicon does not claim that clinical experience with a specific device is necessarily required in order for an expert to have an opinion about it." (Def. Memo. 6). Therefore, the fact that Dr. Weber has not performed a Prolift procedure or personally removed a Prolift mesh is, admittedly, not a basis to disqualify her. The Prolift procedure was created to be an alternative to the traditional procedures using sutures rather than mesh, performed by Dr. Weber, and still performed today. As testified to by Ethicon Medical Affairs Director and creator of the Prolift, Dr. Axel Arnaud, the Prolift is simply a variant of the established pelvic reconstructive techniques. *See* Axel Arnaud 11/15/12 Dep. at 39:19-40:7 (attached hereto as Ex. H). In fact, Dr. Weber does have surgical experience with TVT mesh, and has used mesh to treat prolapse.

[4] Defendants rely on *Tyree v. Boston Sci. Corp.*, No. 2:12-08633, 2014 WL 5486694, at *3 (S.D.W. Va. Oct. 29, 2014), but quoted portion does not address qualifications, but reliability.

See Chmielewski, Weber, et al., *Anterior Colporrhaphy: a randomized trial of three surgical techniques*, Am J Obstet Gynecol 2001; 185:1299-1306 (attached hereto as Ex. I).

Moreover, federal law is clear: an expert witness need not have performed the actual procedure to which she is opining. *See, e.g.*, *Schneider v. Fried*, 320 F.3d 396, 399-400 (3d Cir. 2003) (reversible error to hold expert not qualified for inexperience with a particular medical procedure because physician had "broad knowledge of heart conditions" generally, "own experience" in related medical specialty and familiar with medical literature); *Lavespere v. Niagara Mach. & Tool Works, Inc.*, 910 F.2d 167, 176-77 (5th Cir. 1990) (holding expert with "impressive" academic credentials qualified to testify, despite no actual experience with specific product; "he learned everything he knew about the device and safety systems suitable for it through reviewing technical literature rather than through hands-on experience")[5]; *Cribbs v. Hobart Corp.*, 951 F.2d 348 (6th Cir. 1991) (same). Although this may be a subject of cross-examination, it is not a basis to preclude opinions. Indeed, even Ethicon has recognized that the opinions of surgeons who do not use mesh for prolapse repairs are absolutely valid. For example, in selecting surgeons to perform a design validation usability study on the Prosima, another Ethicon pelvic mesh device to treat prolapse, they were seeking surgeons who "perform transvaginal prolapse repairs…with or without mesh," and "[n]ot an active/experienced user of prolapse repair systems such as Prolift…" *See* May 2006 Emails re "Mint Usability Study for May," ETH.MESH.00926263-267 at 00926267 (attached hereto as Ex. J).

Dr. Weber had extensive credentials in this area before and apart from her study of the Prolift as an expert. For example, in 2001 Dr. Weber was the lead author on the study titled *Anterior Colporrhaphy: a randomized trial of three surgical techniques*, Am J Obstet Gynecol

[5] *Abrogated in part on unrelated grounds, Little v. Liquid Air Corp.*, 37 F.3d 1069 (5th Cir. 1994) (clarifying summary judgment standard for product liability cases).

2001; 185:1299-1306 (Ex. I), in which alternative methods of treating prolapse, including traditional colporrhaphy, and the use of synthetic graft material, were compared and contrasted. This landmark study by Dr. Weber – the first randomized controlled trial to compare mesh and suture repairs of prolapse – has been cited widely in the medical literature, and in Ethicon's own documents. *See infra*.

Thereafter, in 2011, Dr. Weber and her co-authors re-evaluated the data from the 2001 Study, based on the evolving literature which places the emphasis on subjective and functional quality of life outcomes, rather than anatomic outcomes. Based on this criteria, the use of mesh showed no significant functional benefit as compared to suture repair with native tissue. Chmielewski, Weber, et al., *Reanalysis of a randomized trial of three techniques of anterior colporrhaphy using clinically relevant definitions of success*," Am J Obstet Gynecol 2011; 205(1): 69.e1-8 (attached hereto as Ex. K). This 2011 article was cited with approval and adopted by The American Urogynecologic Society ("AUGS") and ACOG, the largest and preeminent medical societies of urogynecologists and gynecologists in the world, in Joint Committee Opinion 513. *See* AUGS/ACOG Joint Committee Op. 513, at 6, Ref. Nos. 22-23 (attached hereto as Ex. L).

Dr. Weber was also an author of the ACOG Practice Bulletin No. 79, February 2007, titled *Pelvic Organ Prolapse*, in which the various methods of staging and evaluating prolapse are described in detail, as well as the various methods for treating pelvic organ prolapse, including the use of synthetic material such as mesh. *See* ACOG Practice Bulletin No. 79 (Feb. 2007) (attached hereto as Ex. M). In that Practice Bulletin, which provides Clinical Management Guidelines to ACOG members, the following pointed recommendation was made:

> Although several studies have evaluated anterior colporrhaphy with and without mesh or graft materials of different types (71-79),

> because of heterogeneity of material studied, small sample sizes, and short-term follow-up, it is not possible to draw definitive conclusions about the risk versus the benefit of absorbable or permanent synthetic materials in anterior colporrhaphy. **Given the limited data and frequent changes in the marketed products (particularly with regard to type of mesh material itself, which is most closely associated with several of the postoperative risks, especially mesh erosion), the procedures should be considered <u>experimental</u> and patients should consent to surgery with that understanding.**

Id. at p. 468 (emphasis added). The ACOG publication cites to extensive literature and discusses the core Prolift issues, including (1) the use of trocars; (2) complications from mesh including contraction, vaginal shortening and narrowing and fistula; (3) treatment of mesh complications; (4) the "key role" played by the characteristics of the material in the risk-benefit ratio, particularly pore size; (5) the role of chemical coatings of mesh in the risk of complications; (6) the high rates of complications despite the use of polypropylene; and (7) the key role of the "type of mesh material" in causing complications. *Id.* at 467-468. This important peer reviewed ACOG publication was written by Dr. Weber and published by ACOG **<u>after</u> Dr. Weber stopped practicing medicine,** and **<u>before</u> she was ever approached to be an expert in this litigation**, and more than validates her credentials as a respected expert in this field – which thoroughly rebuts Defendants' distortion of Dr. Weber's professional history. *Id.*

Moreover, the testimony of Ethicon employees and the contents of key Ethicon documents confirm Ethicon's recognition of Dr. Weber as a top expert in this field. For example, on September 18, 2012 (months after Dr. Weber's general report was served), Corporate Representative Piet Hinoul of Ethicon medical affairs testified:

> Q. You certainly hold Anne Weber in high esteem. That's somebody you respect. Correct?
>
> A. Yes.

See Piet Hinoul 9/18/12 Dep. at 704:17-19 (attached hereto as Ex. N). In addition, Ethicon's 2007 Prolift Professional Education Slide deck cites to two of Dr. Weber's publications – including a 2001 publication and a 1997 publication – with regard to the fascia of the anterior compartment and the method of dissection and plication of the anterior compartment during anterior colporrhaphy. *See* Excerpts from 2007 Prolift Professional Education Slide Deck (attached hereto as Ex. O).

In sum, the totality of Dr. Weber's qualifications is more than sufficient.

IV. DR. WEBER'S METHODS ARE RELIABLE

Only two of the other objections actually identify and challenge a specific methodology, and Dr. Weber's method is reliable as to these two issues.

A. Dr. Weber's Methodology regarding "Prolift Design" is Reliable

Defendants assert vaguely that Dr. Weber's methodology regarding the "Prolift's design," its characteristics (*e.g.*, pore size, weight, porosity, degradation and foreign body reaction), and a safer alternative procedure and devices are unreliable. However, defendants fail to ever identify or specify what methodology defendants believe to be flawed. Instead, defendants simply rehash their arguments regarding Dr. Weber's qualifications.

Generally, Dr. Weber's methodology regarding the design of the Prolift and its characteristics is based on her clinical experience and relevant literature, as detailed in her extensive report, and so is reliable. *See Carlson v. Boston Sci. Corp.*, No. 2:13-CV-05475, 2015 WL 1931311, at *11 (S.D.W. Va. Apr. 28, 2015) ("Drawing on his clinical experience and review of relevant literature is a sufficiently reliable method of forming the opinion that the risks of polypropylene outweigh the benefits."). The Prolift is a procedure developed as an alternative to suture repair. Dr. Weber, a leading expert on the surgical repair of prolapse, and author of an important ACOG Practice Bulletin about the use of suture and mesh to treat prolapse, is well-qualified to testify and applies reliable methods with regard to the defendants' failure to adequately study the Prolift procedure. Dr. Weber's medical opinions in this area are well-supported.

The only substantive critique of Dr. Weber's methodology raised is defendants' claim that Dr. Weber's opinions regarding degradation lack foundation. Plaintiff does not intend to elicit on direct examination an opinion regarding degradation. And in any event, defendants'

claim is incorrect. If defendants inject degradation into a trial, Dr. Weber's opinions on the subject are reliable as they are based on the following:

- A 2010 scientific article (*See* Clavé, et al., *Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants*, Int. Urogynecol J.,) 21:261-270 (Inter'l Urogynecological Assoc. Jan. 2010) (attached here to as Ex. P);

- Ethicon's own documents and research (*E.g.*, Nov. 16, 2012 Post-op Complications Workshop PowerPoint; May 18, 2011 PA Consulting Investigating Mesh Erosion PowerPoint, Slide 1, citing Liebert, Chartoff, et al., J Biomed Mater Res. 1976 Nov., 10(6):939-51; WL Jongeboed & JFG Worst, Documenta Opthalmologica; Vol. 64, No. 1, 143-152; Images on file, Prof. Bernd Klosterhalfen, *Technischer Leiter Pathohistologie, Aachen*; Costello CR, *Materials characterization of explanted polypropylene hernia meshes*, J. Biomat. Res. B. Appl. Biomater. 2007; 83:44-9) (attached hereto as Exs. Q & R); and

- The testimony of Ethicon designee, Dr. Martin Weisberg, who admitted that mesh particles are released during the cutting of the mesh. (*See* Martin Weisberg, M.D. Dep. Tr. 148:5-15) (attached hereto as Ex. S).

B. Dr. Weber's Methodology regarding "Pre-Market Testing" is Reliable

Defendants also assert that Dr. Weber's methodology regarding the "pre-market testing" of the Prolift is unreliable because it is a "personal opinion" lacking an objective standard. In this context, defendants do not disclose the fact that they did **no** clinical study of the Prolift System, as marketed, before going to market. *See* Piet Hinoul 9/18/12 Dep. at 727:1-4 (attached hereto as Ex. N). Dr. Weber is qualified to opine that Ethicon did not conduct adequate clinical studies of the Prolift, because of her extensive experience designing, conducting and evaluating clinical trials, including her work at the Cleveland Clinic, the NIH, and in conducting the first

randomized trial comparing mesh and non-mesh treatments for prolapse, as well as her 2007 ACOG publication, which discusses the "limited data" in this area. *See* Exs. A, I, M.[6]

V. DR. WEBER'S OPINIONS RELEVANT & HELPFUL TO THE JURY

Defendants frame their remaining objections as going to qualifications or methodology, but in reality their claims go to relevancy, helpfulness to the jury or undue prejudice. Further, none of these arguments justify the relief defendants seek – to bar all of Dr. Weber's opinions.

A. Ethicon's "Credo"

Dr. Weber does not intend to offer any opinion on direct regarding defendants' "credo."

B. Ethicon's State of Mind

Plaintiff does not intend to elicit improper "state of mind" testimony from Dr. Weber during direct examination. However the exact parameters of defendants' objection are unclear at this time. To the extent defendants seek to expand the prohibition on "state of mind" testimony to bar testimony relevant to foundational knowledge or notice relied on as a basis of an opinion, plaintiffs oppose defendants' motion.

C. Ethicon's Unethical Clinical Practices

Dr. Weber does not intend to offer "ethics" opinions on direct examination. However, she is clearly qualified to opine regarding the proper standards and protocols for informed consent in clinical trials, if asked. This is another area specifically addressed in the ACOG publication ("the practices should be considered experimental and **patients should consent** to surgery with that understanding.") (*See* Ex. M).

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[6] Defendants' reliance on *Carlson*, 2015 WL 1931311, at *15 is misplaced. Unlike Dr. Weber here who has extensive experience designing and conducting clinical trials, in *Carlson*, Dr. Shull lacked experience in clinical trials beyond that of "the average pelvic surgeon."

D. Ethicon's Failure to Report Issues to the FDA

Dr. Weber does not intend to offer such "FDA" opinions on direct examination. However, to the extent defendants' motion is an attempt to prevent Dr. Weber from relying on such reports and data therein, the motion is opposed. The issue reports and adverse event reports are relevant and a proper basis for testimony regarding defendants' notice, the type, and the extent of Prolift complications that urogynecologists and other physicians were reporting to Ethicon. Courts have repeatedly held that such evidence may be relied on by experts.[7]

E. To Profit, Ethicon Lowered the Standards for Surgeons it Would Train

Defendants claim that Dr. Weber should not be permitted to testify that Ethicon's criteria for selecting surgeons for Prolift training compromised patient safety – asserting such an opinion is "immaterial." However, courts have held the unusual degree of training undertaken by pelvic mesh manufacturers of physicians is relevant and gives rise to liability for doing so negligently. *E.g.*, *Lemon v. Anon. Physician*, No. 1:04-2083, 2005 WL 2218359, at *2 (S.D. Ind. Sept. 12, 2005) ("medical device manufacturer does not automatically have a duty to properly train...a physician on...use of the device. However, the manufacturer can affirmatively undertake that duty"). As set forth in Dr. Weber's Report, here Ethicon realized that the Prolift procedure was very difficult and initially limited its training program to "highly skilled" pelvic surgeons. *See* Report at pg. 80-81 (attached to Def. Mot., Ex. E). However, to maximize sales Ethicon later expanded its program and began training less skilled surgeons. *Id*. In prior Prolift trials,

[7] *E.g.*, *Mahaney v. Novartis Pharms. Corp.*, 835 F. Supp. 2d 299, 312 (W.D. Ky. 2011) (expert opinion on causation based in part on FDA adverse incident reports held reliable); *Bartlett v. Mutual Pharm. Co., Inc.*, 760 F. Supp. 2d 220, 234 n.7 (D.N.H. 2011) ("this court allowed [plaintiff]'s experts to testify based on the [FDA adverse incident] reports"); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 200 (S.D.N.Y. 2009); *Wolfe v. McNeil-PPC, Inc.*, No. 07–348, 2012 WL 38694, at *3 (E.D. Pa. Jan. 9, 2012); *In re Levaquin Prods. Liab. Litig.*, No. 08–5743, 2010 WL 4676973, at *4 (D. Minn. Nov. 9, 2010).

defendants have sought to shift blame to the implanting surgeon for failing to properly implant the Prolift. Consequently, if Ethicon seeks to assert such a defense (blame the surgeon), it is entirely appropriate for plaintiff to adduce evidence that Ethicon knew the Prolift procedure was extremely difficult for average surgeons, and why that was, yet opened its training program and marketed the Prolift to such surgeons. Dr. Weber has educated and trained many pelvic surgeons (*see* Weber CV, Ex. A), and she is certainly qualified to offer opinions on the level of skill

F. Internal Ethicon Documents are a Proper Basis for Expert Opinion

Defendants speculate that Dr. Weber will summarize internal Ethicon documents and provide an improper "factual narrative" at trial. This claim is legally and factually meritless.

As defendants concede (Def. Memo. 16), an expert is permitted to summarize such documents when they are the factual bases of her opinions. And this Court has previously held, "an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions…." *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-4301, 2014 WL 186872, at *6,16 (S.D.W. Va. Jan. 15, 2014); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 702-03 (S.D.W. Va. 2014) ("an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions'). Plaintiff will only elicit a summary of internal Ethicon documents when necessary and appropriate to explain to the jury the bases of Dr. Weber's opinions.

Significantly, defendants only cite a portion of Dr. Weber's expert report (pg. 165-187), but even that is not a summary "narrative" of documents. Rather, the cited portion of Dr. Weber's report is an analysis of how Ethicon's documents demonstrate its behind-the-scene role in revising and manipulating the supposedly independent randomized study (*i.e.*, the Altman

study) that was published in the New England Journal of Medicine.[8] Dr. Weber's careful analysis of how Ethicon coerced Dr. Altman to alter the results of his "independent" study is a basis for her opinions and analysis of the Altman study, which is a basis for her opinion on the unacceptable risk/benefit profile for the Prolift. As this Court held in *In re Ethicon*, such "statements provide the factual basis for…opinions and are therefore helpful for the jury to understand [the expert's] opinions. 2014 WL 186872, at *16.

G. Dr. Weber Will Not Use Inflammatory Language

Defendants complain that Dr. Weber's methodology is unreliable because allegedly she uses "hyperbolic, unscientific terms." However, defendants conflate the reliable methodology analysis under F.R.E. 702 with the unduly prejudicial analysis under F.R.E. 403. Defendants' objection is predicated on the latter, and in any event is not accurate.

Plaintiff will not elicit inflammatory language from Dr. Weber. Dr. Weber has testified at three different Prolift bellwethers and days of deposition testimony. Yet, defendants rely on out-of-context sound bites from her report. In short, defendants' objection is a non-issue. At the same time, it must be noted that – contrary to defendants' rhetoric – the terms "epidemic" and "test subject" are, clearly, scientific terms. The epidemic scope of the injuries and harm caused by Ethicon's mesh products is palpably demonstrated by: (1) the FDA's 2008 and 2011 public health notifications warning of the "serious complications" associated with transvaginal mesh devices, (2) Ethicon's decision in 2012 to pull several mesh product from the market, (3) the thousands of women injured by defendants who have filed lawsuits before this Court and in other

[8] *See* Altman, *Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse*, N Engl J Med 2011; 364:1826-183 (May 12, 2011). (attached hereto as Ex. T)

jurisdictions, and (4) the FDA's 2016 reclassification of such mesh products to be Class III "high-risk devices."

VI. CONCLUSION

Defendants' motion should be denied for all these reasons.

Dated: May 9, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

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